

Food and Drug Administration, HHS

§ 25.15

- (2) CGMP—Current good manufacturing practice.
- (3) EA—Environmental assessment.
- (4) EIS—Environmental impact statement.
- (5) The act—Federal Food, Drug, and Cosmetic Act.
- (6) FIFRA—Federal Insecticide, Fungicide, and Rodenticide Act.
- (7) FONSI—Finding of no significant impact.
- (8) GLP—Good laboratory practice.
- (9) GRAS—Generally recognized as safe.
- (10) HACCP—Hazard analysis critical control point.
- (11) IDE—Investigational device exemption.
- (12) IND—Investigational new drug application.
- (13) INAD—Investigational new animal drug application.
- (14) NADA—New animal drug application.
- (15) NDA—New drug application.
- (16) NEPA—National Environmental Policy Act of 1969.
- (17) OTC—Over-the-counter.
- (18) PDP—Product development protocol.
- (19) PMA—Premarket approval application.

[62 FR 40592, July 29, 1997, as amended at 64 FR 399, Jan. 5, 1999]

§ 25.10 Policies and NEPA planning.

(a) All FDA's policies and programs will be planned, developed, and implemented to achieve the policies declared by NEPA and required by CEQ's regulations to ensure responsible stewardship of the environment for present and future generations.

(b) Assessment of environmental factors continues throughout planning and is integrated with other program planning at the earliest possible time to ensure that planning and decisions reflect environmental values, to avoid delays later in the process, and to avoid potential conflicts.

(c) For actions initiated by the agency, the NEPA process will begin when the agency action under consideration is first identified. For actions initiated by applicants or petitioners, NEPA planning begins when FDA receives from an applicant or petitioner an EA or a claim that a categorical exclusion

applies, or when FDA personnel consult with applicants or petitioners on the NEPA-related aspects of their requested actions. FDA may issue a public call for environmental data or otherwise consult with affected individuals or groups when a contemplated action in which it is or may be involved poses potential significant environmental effects.

(d) Environmental documents shall concentrate on timely and significant issues, not amass needless detail.

(e) If a proposed action for which an EIS will be prepared involves possible environmental effects that are required to be considered under statutes or Executive Orders other than those referred to under "Authority" in this part, these effects shall be considered in the NEPA review, consistent with 40 CFR 1502.25 and the HHS General Administration Manual, part 30: Environmental Protection.

Subpart B—Agency Actions Requiring Environmental Consideration

§ 25.15 General procedures.

(a) All applications or petitions requesting agency action require the submission of an EA or a claim of categorical exclusion. A claim of categorical exclusion shall include a statement of compliance with the categorical exclusion criteria and shall state that to the applicant's knowledge, no extraordinary circumstances exist. Failure to submit an adequate EA for an application or petition requesting action by the agency of a type specified in § 25.20, unless the agency can determine that the action qualifies for exclusion under §§ 25.30, 25.31, 25.32, 25.33, or 25.34, is sufficient grounds for FDA to refuse to file or approve the application or petition. An EA adequate for filing is one that addresses the relevant environmental issues. An EA adequate for approval is one that contains sufficient information to enable the agency to determine whether the proposed action may significantly affect the quality of the human environment.

(b) The responsible agency officials will evaluate the information contained in the EA to determine whether it is accurate and objective, whether